Marked-up copies of the replacement specification paragraphs and the foregoing amended claims are enclosed herewith.

REMARKS

The Official Action dated October 2, 2001, has been carefully considered. In view of the foregoing amendments and these remarks, favorable reconsideration and allowance of this application are respectfully requested.

The Official Action requires restriction between four (4) groups of claims that are alleged to be patentably distinct, as follows:

Group I, claims 1-12, 16, 17, 19, and 27-32, directed to a cancer vaccine comprising a polypeptide of the CD55 family and a method of treating a patient with cancer;

Group II, claims 13-15, directed to a cancer vaccine comprising a nucleic acid of the CD55 family;

Group III, claims 20-24, directed to an isolated 791Tgp72 antigen and composition; and

Group IV, claim 26, directed to a method of isolating 791Tgp72 antigen from cells.

Furthermore, claims 1-12, 16, 17, 19, and 27-32 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking adequate enablement.

Finally, the Draftsperson has objected to certain informalities in the drawings.

The above listed objections and rejections constitute the entirety of the grounds set forth in the Official Action dated October 2, 2001, for refusing allowance of this application. Each of the rejections and objections is respectfully traversed for the reasons set forth below.

In accordance with the present amendments, claims 1, 4, 13, 14, 27, 31 and 32 have been amended to further define the scope of the present invention. Claims 1, 4, 14, 27, and 32, as amended, recite that the anti-cancer vaccines of the invention contain a fragment of a polypeptide of the CD55 family or a derivative thereof, or that the fragment or derivative has part of the amino acid sequence of Figures 10 or 11. Support for these amendments is provided in the claims as originally filed, *inter alia*. Claims 1, 13, and 31 as amended herein specify that the immune response induced by the vaccine of the invention is a T cell response. Support for these amendments can be found in the claims as originally filed, and in the paragraph bridging page 6 and 7 and at page 13, line 15 of the present specification, *inter alia*. Accordingly, it is believed that the amendments to claims 1, 4, 13, 14, 27, 31, and 32 introduce no new matter into the present application.

New claims 33 through 36 are also submitted herewith. New claim 33 specifies that the vaccine is a therapeutic vaccine. Support for claim 33 can be found, e.g., throughout the greater

part of the specification, which is largely directed towards the treatment, rather than the prevention, of tumors. See, for example, the paragraph bridging pages 12 and 13, *inter alia*. New claim 34 specifies that the T cell epitope is a T cell epitope of the CD55 family polypeptide. Support for this claim is provided, e.g., at page 37 of the present specification *inter alia*. New claims 35 and 36 specify particular types of T cell response. Support for these claims can be found, e.g., in the paragraph bridging pages 12 and 13, and in claim 15 as originally filed, *inter alia*. Accordingly, it is believed that no new matter has been introduced as a result of the addition of new claims 33 through 36.

Applicants also submit herewith replacement paragraphs for four paragraphs in the specification, beginning on page 5 at line 28 and ending on page 6 at line 23. The term "791Tgp72" has been substituted for "T791Tgp72" throughout these paragraphs. This amendment is intended to rectify several occurrences of an apparent typographical error, and accordingly introduces no new matter into the application.

Turning attention to the Restriction Requirement, Applicants respectfully submit that this requirement is improper for failure to comply with the relevant provisions of the Manual of Patent Examining Procedure (M.P.E.P.) pertaining to unity of invention determinations.

The present application was filed under 35 U.S.C. §371 as a U.S. national stage application under the Patent Cooperation

Treaty (PCT). As stated in § 1893.03(d) of the M.P.E.P.:

> Examiners are reminded that unity of invention (not restriction) practice is applicable in international applications (both Chapter I and II) and in national stage (filed under 35 U.S.C. 371) applications...
>
> The principles of unity of invention are used to determine the types of claimed subject matter and the combinations of claims to different categories of invention that are permitted to be included in a single international or national stage patent application. The basic principle is that an application should relate to only one invention or, if there is more than one invention, that applicant would have a right to include in a single application only those inventions which are so linked as to form a single general inventive concept. A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art... Note also examples 1-17 of Annex B part 2 of the PCT Administrative Instructions as amended 01 July 1992 contained in Appendix AI of the M.P.E.P.

The present invention is broadly directed to the preparation of cancer vaccines comprising polypeptides of the CD55 family, preferably 791Tgp72 polypeptides. *See, e.g.,* the specification at page 1, lines 4-9 and at page 4, lines 10-16. Therefore, all of the pending claims contain common technical features, one of which corresponds to polypeptides of the CD55 family. Thus, Applicants respectfully submit that all of the pending claims have unity of invention, because they share one

of the special technical features that define the invention. In this connection, it is noteworthy that during the international stage of this application, the subject matter of all of the claims then pending i.e., original claims 1-26, was treated as one inventive concept, as can be seen in the International Preliminary Examination Report (IPER) under PCT Article 36 and Rule 70, dated July 14, 2000.

Applicants respectfully take exception to the assertion in the Official Action that the use of 791Tgp72 in a cancer vaccine is included in the prior art, in view of the disclosure of Durrant, L.G., *Anti-Cancer Drugs*, 1997, *8*, 727-733 (hereinafter Durrant 1997). This same reference is categorized in the International Search Report as merely defining the general state of the art which is not considered to be of particular relevance. The abstract of Durrant 1997 simply states, that among other agents anti-idiotype based vaccines for colorectal target antigen 791Tgp72 are in clinical development. Perusal of the second column at page 729 reveals that the vaccine is not based on the 791Tgp72 antigen, *per se*, but rather on 105AD7, a human monoclonal anti-idiotypic antibody which mimics 791Tgp72. Such antibody molecule includes an effector function mediated by the constant region of heavy chains (and thus, not present in cell-associated antigens) which generally results in removal of antigen from the body. Thus, Durrant 1997 does not place the use of 791Tgp72 as a cancer vaccine in the possession of the public. Accordingly, Applicants respectfully submit that the technical

feature corresponding to the use of 791Tgp72 antigen as a cancer vaccine has not been disclosed in Durrant 1997.

Furthermore, the above-referenced PCT Administrative Instructions quite clearly state that no lack of unity exists between a protein and the DNA sequence encoding the protein. *See* Example 17. Unity of invention, therefore, clearly exists at least between groups I and II, a cancer vaccine comprising a polypeptide of the CD55 family and a cancer vaccine comprising a nucleotide of the CD55 family. By syllogism, then, the unity of invention between groups I and II extends to groups III and IV.

For all of the foregoing reasons, the restriction requirement fails to comply with the established United States Patent and Trademark Office practice of following the international rules regarding unity of invention in the prosecution of applications filed under §371. Accordingly, Applicants respectfully request that the restriction requirement be withdrawn upon reconsideration, and that all the pending claims be examined together in this application.

In order to be fully responsive to the above-mentioned requirement, however, Applicants affirm the provisional election with traverse of the subject matter of Group I, that is, claims 1-12, 16-17, 19, and 27-32, for consideration in this application.

Applicants hereby reserve the right to file one or more continuing applications, as provided in 35 U.S.C. § 120, on the

subject matter of any claims finally held withdrawn from consideration in this application.

Applicants respectfully submit that the full scope of all the claims as amended herein is enabled by the present specification. As noted in the MPEP at §2164,

> The information contained in the disclosure of an application must be sufficient to inform **those skilled in the relevant art** how to both make and use the claimed invention. Detailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention. [*Emphasis supplied.*]

In §2164.01, the MPEP continues,

> The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent **coupled with information known in the art** without undue experimentation. [*Emphasis supplied; citation omitted.*]

At §2164.01(a), the MPEP continues:

> It is improper to conclude that a disclosure is not enabling based on an analysis of only one of the [relevant] factors while ignoring one or more of the others. The examiner's analysis must consider all the evidence related to each of these factors, and **any conclusion of nonenablement must be based on the evidence as a whole.** [*Citation omitted, emphasis supplied.*]

Further,

> **The fact that experimentation may be complex does not necessarily make it undue**, if the art typically engages in such experimentation. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. [MPEP § 2164.01, *emphasis supplied, citations omitted.*]

Applicants respectfully submit that those of skill in the art of anti-cancer drug discovery, once apprised of the contents of the present specification, could indeed practice the claimed invention.

The Examiner has objected to the term "vaccine", on the basis that protective immunity has not been demonstrated in the application, and that certain papers published four years before the filing date of the present application express doubts about the likely success of cancer vaccines.

Initially, Applicants note that the claims as presently amended herein do not require protective immunity. A vaccine may be prophylactic (protective) or therapeutic. The specification provides a detailed explanation (summarized below) of why the skilled artisan would expect the agents of claim 1 to be effective in treating tumors. Such agents would indeed function as cancer vaccines. While the vaccines of the invention need not necessarily provide a protective immune response in addition to an anti-cancer therapeutic effect, because the claim does not require this, they may well do so. Consequently, limitation of the claims exclusively to therapeutic vaccines, or to exclude protective vaccines, would be inappropriate.

Applicants further submit that the highly selective quotations from the Ezzell and Spitler papers have caused their proper context to be lost. Rather than teaching that cancer vaccines do not work, these references in fact teach that even four (4) years before applicants' filing date, significant

progress had been made towards successful cancer vaccines.

The Official Action quotes from Ezzell as follows:

> ...tumor immunologists are reluctant to place bets on which cancer vaccine approach will prove effective in the long run and further states that no one is very optimistic that a single peptide will trigger an immune response strong enough to eradicate tumors or even to prevent the later growth of micrometastases among patients whose tumors have been surgically removed or killed by radiation or chemotherapy.

However, this passage is clearly describing an ideal cancer vaccine, i.e., one which will be totally effective in all patients. This level of success in not required for a cancer vaccine to have practical utility. Even very modest success rates in the treatment of high mortality diseases such as cancer can form the basis for regulatory approval. Indeed, Ezzell reports two studies using T cells that achieved tumor shrinkage in a significant number of patients (20% and one third). Moreover, two groups are reported to have entered clinical trials using exactly the same approach as the present application: peptides based on a tumor-specific antigen (see page 48, right hand column, paragraphs 5 and 6).

The Official Action also quotes the following passage from Spitler:

> Ask practising oenologists what they think about cancer vaccines and you're likely to get the following response: "cancer vaccines don't work"...

In context, this passage clearly refers to the fact that, in 1995, no cancer vaccines had received regulatory approval. In

fact, the statement is merely a literary device, set in contrast to the remainder of the article, which reports the exciting progress that had, even in 1995, been made towards cancer vaccines. See, for example, the passage at page 2, left hand column:

> Cancer vaccines have finally reached the stage in technological development where commercial development can be envisioned. Due to the development of monoclonal antibody technology, scientists have now identified and characterized tumor associated antigens and determined their tissue distribution. Their amino acid sequences have been determined and cDNA clones produced permitting production of virtually unlimited quantities of pure antigens for use in vaccine development. Together with these advances in identification and purification of the antigens have been advances in understanding of the immune system, especially MHC I and MHC II antigen presentation and the generation of cytotoxic T cells. ... [emphasis added]

Thus, it is clear from the article as a whole that the author, a medical doctor, regards the idea that "cancer vaccines do not work" to be outdated.

The overall teaching of both Ezzell and Spitler is the same: not that cancer vaccines do not work, as suggested by the Examiner, but that cancer vaccines are an idea whose time appears to have come (cf. the title of Ezzell's paper).

Moreover, the present specification contains ample disclosure to support the effectiveness of the vaccines of the present invention. As described at pages 2-3, 105AD7 (an antibody which mimics, and shares significant sequence homology

with, the tumor specific antigen 791Tgp72) is an excellent immunogen for stimulating anti-tumor T cell mediated immunity. This antibody has entered phase I/II clinical trials, with excellent results.

Similar results have also been achieved using a mouse anti-idiotype antigen, 730. See the present specification at page 37, lines 9-19.

In addition, the Applicants have now identified the sequences of the tumor specific antigen 791Tgp72 which are mimicked by 105AD7 and 730, and identified the 791Tgp72 antigen to have the same sequence as that of one form of CD55. Consequently, a CD55 fragment or derivative based on the T cell epitope which is mimicked by 105AD7 or 730 (*see* page 37 of the present specification for the identification of the epitopes) is confidently predicted to be similarly capable of stimulating anti-tumor T cell mediated immunity. The same holds true for other peptide fragments and derivatives of CD55 which contain T cell epitopes.

It is quite surprising that 791Tgp72/CD55 is a suitable target for a therapeutic T cell mediated immune response, in view of its normal expression on essentially all haematopoietic cells, and its role in protecting these cells from complement-mediated lysis. *See* paragraph bridging pages 41-42 of the present specification.

Apart from its role in protecting normal cells from complement-mediated lysis, CD55 is also thought to protect

cancers from NK cell mediated lysis when overexpressed on tumors (*See* the present specification at page 42, first paragraph).

The roles of CD55 in protecting against complement-mediated and NK cell-mediated lysis is, however, thought to provide a highly significant advantage in using 791Tgp72 / CD55 as a cancer vaccine target. Many previous candidate cancer vaccines have proved ineffective because the cancer has evolved to stop expressing the target tumor-specific antigen, thus avoiding the immune response targeted against that antigen. This problem is discussed in Ezzell at page 48, left hand column, paragraph 4 and is a significant cause of the doubts expressed by Ezzell, and repeated by the Examiner, about whether a single peptide vaccine will be successful. With CD55, however, loss of expression of CD55 by the cancer is expected to make the cells susceptible to another arm of the immune response. *See*, for example, the specification at page 43, final paragraph:

> It remains an interesting prospect to use a molecule which tumours over-express to protect themselves from immune attack as a cancer vaccine. The dichotomy being that if the cell fails to express the molecule it is susceptible to complement mediated and NK lysis and if it does express the antigen it will be killed by CD55 specific T-cells.

Thus there are particular reasons, specific to 791Tgp72/CD55 as a target, why its efficacy as a vaccine is to be expected.

The Official Action also alleges that finding peptides within the CD55 sequence which are capable of inducing an anti-tumor T cell response would impose an undue burden on the skilled artisan. Applicants respectfully submit that this assertion is

incorrect. At the filing date of this application, it was a matter of routine for the skilled artisan to identify T cell epitopes within a given amino acid sequence.

Applicants enclose herewith a copy of Lu et al., (2000) *Cancer Research* 60: 5223-5227. Although this document was published in 2000, it indicates by references to earlier published documents that techniques were available before the filing date for identifying T cell epitopes. In particular, the Examiner's attention is respectfully directed to the following passages:

> Because CTL peptide epitopes are restricted to specific MHC alleles, to design immune therapies for the general population it is necessary to identify epitopes for the most commonly found human MHC alleles. The identification of such epitopes has been based on MHC-peptide-binding assays that are costly and labor-intensive. [Abstract, 3rd and 4th sentences]
>
> In the past, our laboratory has relied on the use of peptide-MHC-binding assays to select potential CTL epitopes from known [tumour associated antigens], before these peptides are tested for *in vitro* CTL induction (17-19, 28, 33-36). [Discussion, first paragraph]

All but two of the references cited in the later passage are from before the filing date of the application, indicating that empirical techniques for identifying T cell epitopes were available as of the filing date of the present application. Although these techniques are indicated to be "costly and labor-intensive", there is no indication that they are uncertain or unreliable. Therefore, the required experimentation does not

represent an undue burden on the skilled person.

Moreover, the thrust of Lu et al. is the use of *in silico* techniques, which were also available at the filing date of the present application, to reduce the amount of experimentation required to identify T cell epitopes. The Examiner's attention is respectfully directed to following passages:

> We report here the use of two computer-based prediction algorithms, which are readily available in the public domain (Internet), to identify *HLA-B7*-restricted CTL epitopes for carcinoembryonic antigen. [Abstract, 5th sentence; emphasis added]
>
> **Epitope Selection and Peptide Synthesis.** We used the combination of two computer algorithms that exist in the public domain and are easily accessible through the Internet. The predictive algorithm, "BIMAS" developed by K. C. Parker and collaborators (20), is available at a web site of the NIH [from footnote - Internet address: http://bimas.dcrt.nih.gov/molbio/ken_parker_combofrom.]. … The second algorithm, "SYFPEITHI" [from footnote - Internet address: http://134.2.96.221/scripts/hlaserver.dll/home.htm], was developed by H. G. Rammensee *et al.* (21) … [Material and Methods, first paragraph]

Reference (20) is to a paper published in 1994, a full five years before the filing date of the application.

Although reference (21) is to a paper published after the filing date of the subject application, it is clear from the corresponding website (in fact now moved to http://www.bmi-heidelberg.com/syfpeithi/) that the algorithms predate the filing date of the subject application. Applicants enclose herewith hard copies of pages from the website: the page labelled A is the

title page and leads (via the link "click here to continue") to the page labelled B; page B has various links, including "epitope prediction" and "information"; the page labelled C shows the epitope prediction page; the page labelled D shows the information page. As can be seen from page C, the epitope prediction algorithms are based on the book "MHC Ligands and Peptide Motifs" by H G Rammensee, J Bachmann and S Stevanovic. Page D shows that this book was published in 1997, well before the filing date of the subject application.

In addition, Southwood et al. (1998) *J. Immunol.*, 160: 3363-3373 (copy enclosed) teach a corresponding algorithm for identifying MHC-II T cell epitopes in protein sequences.

Accordingly, at the filing date of the application, the skilled person would have been well able to identify T cell epitopes within the CD55 / 791Tgp72 amino acid sequence given in the application, using well-established empirical or *in silico* techniques.

Moreover, the Lu paper indicates that the *in vitro* testing of the ability of peptides containing such epitopes to activate T cells *in vitro* is also a matter of routine, and that the results are reflective of the *in vivo* effect of the peptides:

> ...the method for inducing *in vitro* CTL responses that is routinely used in our laboratory results in objective CTL responses in most of the cases in which peptides that represent CTL epitopes are used. [page 5226, right hand column, first paragraph; emphasis added]

The use of the term "objective" in this passage means that the *in vitro* CTL responses are indicative of *in vivo* responses.

Finally, the references D'Amaro et al. (1995) *Human Immunology* 43: 13-18; Davenport et al. (1995) *Immunogenetics* 42: 392-397 and WO97/41440 (copies of these references enclosed) have been cited in the International Search Report and International Preliminary Examination Report on the co-pending application PCT/GB99/00583, on which U.S. Application No. 09/623,063 is based, as disclosing "well known methods for determining possible MHC binding peptides and/or potential T cell epitopes".

The Official Action further attempts to justify the position that the present claims are not enabled by alluding to the alleged unpredictability of protein chemistry, citing various papers, and asserting that "certain positions in the sequence are critical to the three-dimensional structure/function relationship, and these regions can tolerate only conservative substitutions or no substitutions". Consequently, the Official Action alleges, the fragments and derivatives of the invention are not enabled.

This argument in the Official Action, however, does not account for the fact that T cell epitopes are presented by MHC molecules as short peptide fragments, in which the three-dimensional structure of the protein is lost. The fact that a peptide fragment or derivative of the invention may have lost the three-dimensional structure of the native CD55/791Tgp72 antigen is thus wholly irrelevant to its function as a T cell immunogen.

Nevertheless, in an effort to advance prosecution, the term "polypeptide" has been deleted from claims 2, 4-7, and 13. A basis for these amendments is provided in the claims as originally filed, *inter alia*. Accordingly, these amendments introduce no new matter into the present application.

Moreover, since the identification of T cell epitopes in an amino acid sequence involves the identification of certain patterns of "anchor" residues in the sequence, the skilled person will be well aware that non-anchor residues are good targets for mutation. Consequently, it would not require undue experimentation for the skilled person to identify derivatives of the fragments of the invention which are also capable of stimulating an anti-tumor T cell response.

The Examiner's attention is once more respectfully directed to the Lu et al. paper, at page 5226, right-hand column, end of second paragraph. This passage cites reference (38), Zugel et al., (copy enclosed). Zugel et al. teach that derivatives of a T cell epitope may even evoke a greater T cell response than the native sequence (the "heteroclitic effect"), and that such derivatives may be even more effective antigens for malignant tumors than the native antigens. See page 1709, left hand column, final paragraph.

In summary, Applicants respectfully submit that the rejection under 35 U.S.C. §112, first paragraph, is substantively improper; however, it has been fully overcome by the amendments, arguments, and publications submitted herewith. Therefore,

Applicants respectfully request that this rejection be withdrawn upon reconsideration.

The Draftsperson has objected to several informalities in the drawings. Under the provisions of 37 C.F.R. § 1.111(b), when replying to an Official Action,

> [i]f the reply is with respect to an application, a request may be made that objections or requirements as to form not necessary to further consideration of the claims be held in abeyance until allowable subject matter is indicated.

Applicants respectfully submit that the submission of revised drawings is a formal requirement, not related to the further examination of the claims in the present application. Accordingly, Applicants respectfully request that these objections be held in abeyance pending the indication of allowable subject matter.

Applicants believe that the present communication is completely responsive to the Office Action of October 2, 2001. In view of the foregoing amendments and remarks, it is respectfully submitted that all rejections have been overcome.

In the event the Examiner is not persuaded as to the allowability of any claim, and it appears that any outstanding issues may be resolved through a telephone interview, the Examiner is invited to contact the undersigned at the telephone number listed below.

In the event any fee is due in connection with the consideration of this response, the Commissioner is authorized to charge any such fee to the account of the undersigned

attorneys, Deposit Account No. 04-1406.

Applicants believe that the claims as they now stand are in condition for allowance. Accordingly, it is respectfully urged that this application be passed expeditiously to issue.

Respectfully submitted,

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Reg. No. 27,643
Attorney for Applicant

PJH:ksk
Enclosures:

1. Marked-Up Replacement Paragraphs
2. Marked-Up Amended Claims
3. Lu et al., (2000) *Cancer Research* 60: 5223-5227
4. Pages (marked A-D) from the http://www.bmi-heidelberg.com/syfpeithi/ website
5. Southwood et al. (1998) *J. Immunol.*, 160: 3363-3373
6. D'Amaro et al. (1995) *Human Immunology* 43: 13-18
7. Davenport et al. (1995) *Immunogenetics* 42: 392-397
8. International Application No. WO 97/41440
9. U. Zugel et al. (1998) *J. Immunol.*, 161: 1705-1709

REPLACEMENT PARAGRAPHS WITH AMENDMENTS MARKED

Accordingly, in a further aspect, the present invention provides a cancer vaccine comprising 791Tgp72 antigen or a polypeptide of the CD55 family, or a fragment or derivative of [T791Tgp72] 791Tgp72 or of a polypeptide of the CD55 family, wherein the vaccine is capable of inducing an immune response in a patient. The response may be one or more of a T-helper cell response, a cytotoxic T-cell response, an NK cell response and/or an immune response.

In a further aspect, the present invention provides a cancer vaccine comprising nucleic acid encoding 791Tgp72 and/or a polypeptide of the CD55 family, or a fragment or derivative of [T791Tgp72] 791Tgp72 or of a polypeptide of the CD55 family, wherein the vaccine is capable of inducing an immune response in a patient. Again, the response may be one or more of a T-helper cell response, a cytotoxic T-cell response, an NK cell response and/or an immune response.

In a further aspect, the present invention provides the use of 791Tgp72 antigen or a polypeptide of the CD55 family, or a fragment or derivative of [T791Tgp72] 791Tgp72 or of a polypeptide of the CD55 family, in the preparation of a medicament for the treatment of cancer.

In a further aspect, the present invention provides the use of nucleic acid encoding 791Tgp72 antigen or a polypeptide of the CD55 family, or a fragment or derivative of [T791Tgp72] 791Tgp72 or of a polypeptide of the CD55 family, in the

preparation of a medicament for the treatment of cancer.

AMENDED CLAIMS WITH CHANGES MARKED

1. (Amended) A cancer vaccine comprising [a polypeptide of the CD55 family, or] a fragment [or derivative] of a polypeptide of the CD55 family or a derivative thereof, wherein said fragment or derivative contains a T cell epitope, and wherein the vaccine is capable of inducing an immune response in a patient, said immune response being a T cell response.

2. (Amended) A cancer vaccine according to claim 1 wherein [the polypeptide of the CD55 family is, or] the fragment or derivative is of[,] 791Tgp72 antigen.

4. (Twice amended) A cancer vaccine according to claim 1 wherein the [polypeptide,] fragment or derivative has part [or all] of the amino acid sequence of Fig. 10.

5. (Twice amended) A cancer vaccine according to claim 1 wherein the [polypeptide,] fragment or derivative includes part or all of the amino acid sequence consisting of amino acids 97-159 of Fig. 10.

6. (Twice amended) A cancer vaccine according to claim 5 wherein the [polypeptide,] fragment or derivative includes a sequence having at least five amino acids identical with corresponding amino acids of a contiguous stretch of seven amino acids contained within amino acids 121-128 or 151-158 of Fig. 10.

7. (Twice amended) A cancer vaccine according to claim 1 wherein the [polypeptide,] fragment or derivative includes a sequence having at least six amino acids identical with corresponding amino acids of a contiguous stretch of nine amino acids contained within amino acids 83-93 of Fig. 10.

13. (Twice amended) A cancer vaccine comprising a nucleic acid molecule which encodes a [polypeptide,] fragment or derivative as specified in claim 1, wherein the vaccine is capable of inducing an immune response in a patient, said immune response being a T cell response.

14. (Amended) A cancer vaccine according to claim 13 having part [or all] of a nucleic acid sequence as shown in Fig. 10 or Fig. 11.

27. (Amended) A cancer vaccine according to claim 2, wherein the antigen has part [or all] of the amino acid sequence of Fig. 10.

31. (Amended) A cancer vaccine comprising a nucleic acid molecule which encodes an antigen as specified in claim 2, wherein the vaccine is capable of inducing an immune response in a patient, said immune response being a T cell response.

32. (Amended) A cancer vaccine according to claim 31, having part [or all] of a nucleic acid sequence as shown in Fig. 10 or Fig. 11.